Registration Decision RD2012-16

Nosema (Paranosema) locustae Canning

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Registration Decision for *Nosema (Paranosema) locustae* Canning

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Nolo BB Concentrate and Nolo Bait Biological Insecticide, containing the technical grade active ingredient *Nosema (Paranosema) locustae* Canning, which may suppress grasshopper and Mormon crickets in crops and rangelands.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2011-22, *Nosema (Paranosema) locustae* Canning. This Registration Decision[2] describes this stage of the PMRA's regulatory process for *Nosema (Paranosema) locustae* Canning and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2011-22. This decision is consistent with the proposed registration decision stated in PRD2011-22.

For more details on the information presented in this Registration Decision, please refer to PRD2011-22, *Nosema (Paranosema) locustae* Canning, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act*"...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What is *Nosema (Paranosema) locustae* Canning?

Nosema (Paranosema) locustae Canning is a microbial pest control agent that may suppress grasshoppers and Mormon crickets. The spores of this microorganism are ingested by the target pest and then develop primarily in the insect's fat cells. In doing so, the microorganism competes with the host for the energy reserves and as a result the host becomes weak and eventually dies.

The end-use product, Nolo Bait Biological Insecticide, is a commercial class insecticide product that contains *Nosema (Paranosema) locustae* Canning as the active ingredient. The end-use product exists as a bait formulation. The product will be applied on crop and rangeland.

Health Considerations

Can Approved Uses of *Nosema (Paranosema) locustae* Canning Affect Human Health?

***Nosema (Paranosema) locustae* Canning is unlikely to affect human health when Nolo Bait Biological Insecticide is used according to label directions.**

Exposure to *Nosema (Paranosema) locustae* Canning may occur during handling of Nolo Bait Biological Insecticide. When assessing health risks, several key factors are considered: the microorganism's biological properties (for example, production of toxic byproducts); reports of any adverse incidents; its potential to cause disease or toxicity as determined in toxicological studies; and the likely levels to which people may be exposed relative to exposures already encountered in nature to other strains of the microorganism. Toxicology studies in laboratory animals describe potential health effects from large doses for the purpose of identifying any potential to cause disease or toxicity. No significant toxicity and no signs of causing diseases were observed when *Nosema locustae* was tested on laboratory animals, but it tested positive in a sensitization study. Besides the microbial pest control agent, wheat present in the end-use product is known to be an allergen and must be labelled as such (in other words, Wheat Allergen). Recommended Personal Protective Equipment, exposure mitigating, and hygiene statements present in the product label are adequate to protect human health when label directions are followed.

Residues in Water and Food

Dietary risks from food and water are not of concern.

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for the *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value determines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Nosema (Paranosema) locustae Canning spores occur naturally in soils as they enter the environment from infected grasshoppers. The use of Nolo Bait Biological Insecticide, which may suppress grasshoppers and Mormon crickets in croplands and rangelands, is not expected to significantly increase natural environmental background levels of this microorganism because *Nosema locustae* is sensitive to sunlight and heat and is decomposed by other microorganisms, and therefore has low environmental persistence. The spores are not toxic or infective to plants; do not persist on vegetation; and this species is not known to produce any secondary metabolites of toxicological concern. Furthermore, no signs of toxicity or disease were observed when *Nosema locustae* was administered orally to rats. The establishment of an MRL is, therefore, not required for *Nosema locustae* as the likelihood of residues contaminating food and drinking water supplies is negligible to non-existent. As such, dietary exposure and risks are minimal to non-existent.

Occupational Risks From Handling Nolo Bait Biological Insecticide

Occupational risks are not of concern when Nolo Bait Biological Insecticide is used according to label directions, which include protective measures.

Users of Nolo Bait Biological Insecticide can come into direct contact with *Nosema (Paranosema) locustae* Canning on the skin, in the eyes, or by inhalation. Pulmonary toxicity, dermal irritation, eye irritation and sensitization studies using *Nosema locustae* in animals have shown low toxicity, no irritation, and a potential for sensitization. Repeated exposure of occupational workers to high concentrations of *Nosema locustae*, as with any other microorganism, can potentially lead to the development of allergic reactions. The signal words "POTENTIAL SENSITIZER" and precautionary statement "May cause sensitization" are required on the product label to warn workers of this potential hazard. Besides the microbial pest control agent, wheat present in the end-use product is known to be an allergen and must be labelled as such (in other words, Wheat Allergen). To minimize occupational risk, the label will specify that users exposed to Nolo Bait Biological Insecticide must wear gloves, long-sleeved shirts, long pants, shoes plus socks, eye-wear and a NIOSH approved respirator/mask (with any N, P, R or HE filter).

For bystanders, exposure is considered negligible since the application sites are croplands and rangelands and the product is applied as a bait. On the basis of the low toxicity/pathogenicity profile for *Nosema locustae*, Nolo Bait Biological Insecticide is unlikely to pose an undue risk when bystanders are exposed. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When *Nosema (Paranosema) locustae* Canning Is Introduced Into the Environment?

Environmental risks are not of concern.

Nosema (Paranosema) locustae Canning spores occur naturally in soils as they enter the environment from infected grasshoppers. The use of Nolo Bait Biological Insecticide, which may suppress grasshoppers and Mormon crickets in croplands and rangelands, is not expected to significantly increase natural environmental background levels of this microorganism because *Nosema locustae* is sensitive to sunlight and heat and is decomposed by other microorganisms, and therefore has low environmental persistence. Therefore, it is unlikely that the application of Nolo Bait Biological Insecticide will significantly increase the levels of infective, viable persistent *Nosema locustae* that would adversely affect the dynamics of an ecosystem. There have been no reports of adverse ecological effects in the United States from the application of this biopesticide which was first registered there in 1980.

From the available data and information on the effects of *Nosema locustae* to terrestrial/aquatic organisms, there is reasonable certainty that no harm will be caused to birds, fish, wild mammals, terrestrial and aquatic arthropods, non-arthropod invertebrates, plants or to other non-target microorganisms from the use of Nolo Bait Biological Insecticide. It is unlikely that *Nosema locustae* will adversely affect non-target organisms because it is an obligate parasite of grasshoppers and crickets. The use of Nolo Bait Biological Insecticide will not pose significant environmental risk when used according to label instructions.

Value Considerations

What Is the Value of Nolo Bait Biological Insecticide?

Nolo Bait Biological Insecticide has value in that it may suppress grasshoppers and Mormon crickets in crop and rangeland when applied at a minimum rate of 1.12 kg per hectare. One advantage of Nolo Bait Biological Insecticide is that *Nosema locustae* has little effect on beneficial and other non-target organisms. Therefore, in addition to use in organic production, Nolo Bait Biological Insecticide may be useful in environmentally sensitive areas were conventional insecticides cannot be used and reliable, immediate control is not critical. Nolo Bait Biological Insecticide is compatible with current management practices and conventional crop production systems.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Nolo Bait Biological Insecticide to address the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

Human Health

Because of concerns with users developing allergic reactions through repeated high exposure to *Nosema (Paranosema) locustae* Canning, anyone handling or applying Nolo Bait Biological Insecticide must wear waterproof gloves, a long-sleeved shirt, long pants, and shoes plus socks. In addition, mixers/loaders and applicators must wear a NIOSH approved respirator/mask (with any N, P, R or HE filter), and eye-wear.

Since these quantitative analyses for bacterial contaminants were not successfully performed and limits were not set, it cannot be assured that Nolo Bait Biological Insecticide is free from mammalian pathogens. Therefore, the Nolo Bait Biological Insecticide label now includes explicit statements that prevent the product from direct contact with food commodities.

Environment

As a general precaution, handlers are directed to not contaminate irrigation or drinking water or aquatic habitats by cleaning of equipment or by disposing of wastes. In addition, aerial application is permissible only when meteorological conditions at the treatment site allow for complete and even crop coverage.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2011-22 — *Nosema (Paranosema) locustae* Canning) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, healthcanada.gc.ca/pmra) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.